UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,995	10/05/2001	John P. McKearn	CU-2560 RJS	4037

7590 02/22/2002

Richard J Streit
Ladas & Parry
Suite 1200
224 South Michigan Avenue
Chicago, IL 60604

EXAMINER	
PATEL, SUDHAKER B	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/857,995	John P. McKearn et al
Examiner	**Art Unit**
Sudhaker Patel	1624

-- Th MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 1, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-106* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-106* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) (in part)1-3,28-46,71-102, 103,105, drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Anastrozole together with radiation for treatment of neoplasia.

Group II, claim(s) (in part)1-3,28-46,71-102, 4,9,23,47,52,66, drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Capecitabine,Gemcitabine or Vinorelbine together with radiation for treatment of neoplasia.

Group III, claim(s)(in part)1-3,28-46,71-102,-5,48, drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow

mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Cell Pathway CP-461 together with radiation for treatment of neoplasia. .

Group IV, claim(s)(in part)1-3,28-46,71-102, 6,17,49,60 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Docetaxel or Pacclitaxel together with radiation for treatment of neoplasia.

Group V, claim(s)(in part)1-3,28-46,71-102, 7,50 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Doxorubicin together with radiation for treatment of neoplasia.

Group VI, claim(s)(in part)1-3,28-46,71-102, 8,51 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Fluoxymestrine together with radiation for treatment of neoplasia.

Group VII, claim(s)(in part)1-3,28-46,71-102,10,53 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow

mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Goserelin together with radiation for treatment of neoplasia.

Group VIII, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Irinotecan or Topotecan together with radiation for treatment of neoplasia.

Group IX, claim(s)(in part)1-3,28-46,71-102, 12,13,15,55,56,58 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Ketoconazole, Letrozole or Levamisole together with radiation for treatment of neoplasia.

Group X, claim(s)(in part)1-3,28-46,71-102, 14,57 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Leucovorin together with radiation for treatment of neoplasia.

Group XI, claim(s)(in part)1-3,28-46,71-102, 16,59 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow

mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Megestrol together with radiation for treatment of neoplasia.

Group XII, claim(s)(in part) 18,22,61,65 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Ralixifen, Tamoxifen or Toremifen together with radiation for treatment of neoplasia.

Group XIII, claim(s)(in part)1-3,28-46,71-102, 19,62 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Retinoic acid together with radiation for treatment of neoplasia.

Group XIV, claim(s)(in part)1-3,28-46,71-102 20,63 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Retinoic acid together with radiation for treatment of neoplasia.

Group XV, claim(s)(in part)1-3,28-46,71-102, 24,67 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow

mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Selenium(Slenomethione) together with radiation for treatment of neoplasia.

Group XVI, claim(s)(in part)1-3,28-46,71-102, 26,69 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Sulindac sulfone together with radiation for treatment of neoplasia.

Group XVII, claim(s)(in part)1-3,28-46,71-102, 25,68 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Ursodeoxycholic acid together with radiation for treatment of neoplasia.

Group XVIII, claim(s)(in part)1-3,28-46,71-102, 27,70 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Eflornithine(DFMO) together with radiation for treatment of neoplasia.

Group XIX, claim(s)(in part), drawn to 1-3,28-46,71-102, 104,106 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of

bellow mentioned Group A)., and they have the generic core : " ***Heterocycle C-SO2-C-nonheterocycle***" Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 and Calcium carbonate together with radiation for treatment of neoplasia.

Group XX, claim(s)(in part)1-106, drawn to other compositions, a method use, and method of making composition of MMP inhibitors(***one group from MMP Groups A). to J***). and more than one antineoplastic agents with or without radiation for treatment of neoplasia. If this group is elected, further restriction/election will be required, and a single species with specific and exact details related to structure/composition and make up must be disclosed as there are many unknowns.

2. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The chemical structure(s) of the composition and its make up are different and are nonequivalent to each other.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In addition to multiples of different molecules involved and as represented for ***Antineoplastic agents***, following groups of ***MMP inhibitors*** are involved in the make up(s) of various inventions.

The Matrix Metalloproteinase***(MMP) inhibitors*** themselves can be grouped in the following way, each group having different chemical structure:

MMP Group A). Having core as : **Sulfone**: ***Heterococyle C-SO2-C-Non-heterocyle*** i.e. compounds # 1,2,6,7,8,14,15,16,17,18,20.

MMP Group B). Having core as: **Sulfonamide**: ***Heterocycle C-SO2-N Heterocyle*** i.e. compounds # 3,4 of claim 29.

MMP Group C). Having core as: **Sulfonamide**: ***Non-heterocycle C-SO2-N Heterocycle*** i.e. compound # 5 of claim 29.

MMP Group D). Having core as: ***Non-heterocycle and non-aryl hydroxy amine-CO----CO-NH-CH3*** i.e. compound 9 of claim 29

MMP Group E). Having core as: ***Non-heterocyclic aryl acid*** i.e. compound # 10 of claim 29.

MMP Group F). Having core as: ***6-membered Heterocycle with 2 heteroatoms of which one atom is N-SO2-C nonheterocyle*** i.e compound # 11 of claim 29

MMP Group G). Having core as : ***Substituted amino tetracycline*** i.e. compound # 12 of claim 29.

MMP Group H). Having core as: ***Substituted imidazole*** i.e. Chiroscience D-2163 compound # 13 of claim 29.

MMP Group I). Having core as: ***6-membered heterocycle pyran C-SO2-C nonheterocycle*** i.e. compounds # 19,23,24 of claim 29.

MMP Group J). Having core as: ***Heterocycle C-SO2-C nonheterocycle diphenyl sulfide*** i.e. compounds # 21,22 of claim 29.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner: Various species of MMP themselves are non-equivalent to each other in addition to different molecule as presented for multiples of Antineoplastic agents.

The following claim(s) are generic: 1, 29,44,87.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: They represent different make ups for simple or complex combination(s)(more than one MMP inhibitors or Angioplastic agents) with and without radiation, and thus represent multiples of inventions.

6. A telephone call was made to Mr. R.J.Streit on 2/13/02 to request an oral election to the above restriction requirement which is closely related & similar to INTERNATIONAL SEARCH REPORT , but did not result in an election being made.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc.Tech. whose telephone number is (703) 308 4709. The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716.

A facsimile center has been established for Group 1600. The hours of operation Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Sp/February 21, 2002.

MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GRO[illegible]